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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,407	12/12/2001	Edward A. Rhad	END-795	3685

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,407

Applicant(s)

RHAD ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/19/04 has been entered.

Claim Objections

2. Claim 15 objected to because of the following informalities: line 6 uses the British variation of "artifact". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,431,426 to Groshong et al.

In regards to claims 5 and 6, Groshong et al. discloses a thermoplastic (Col. 5, lines 5 - 8) elongated substantially tubular member having a distal end (14), a proximal end (Col. 6, line 14), a longitudinal axis there between, and a side port (12; Col. 40 - 42) on the member; a sharpened closed

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distal tip (Col. 6, lines 3 – 5) attached to the distal end of the tubular member having a hollow cavity filled with a material which will leave an artifact (Col. 6, lines 5 – 8) spaced distally of the side port. The tubular member is considered to be a needle in that it is a hollow instrument for introducing material into or removing material from the body (Merriam-Webster's, 10th ed.).

5. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0082519 A1 to Miller et al.

In regards to claim 15, Miller et al. discloses a biopsy device which is compatible for use with a magnetic resonance imaging machine comprising: a non-metallic elongated substantially tubular needle [0062] having a distal end, a proximal end, a longitudinal axis there between, a cutter lumen (27), a vacuum lumen (17)[0061], a side port (25) for receiving a tissue sample [0059]; a sharpened distal tip (16) for insertion within tissue [0057], the sharpened distal tip attached to the distal end of the needle and comprising a material which will leave an artifact under magnetic resonance imaging [0062]; and a cutter (11), movable within the cutter lumen [0063].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 8 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 5,534,778 to Loos et al.

In regards to claims 5 and 8 – 14 , Miller et al. discloses a biopsy device which is compatible for use with a magnetic resonance imaging machine comprising: a non-metallic elongated substantially tubular needle [0062] having a distal end, a proximal end, a longitudinal axis there between, a cutter lumen (27), a vacuum lumen (17)[0061], a side port (25) for receiving a tissue sample [0059]; a sharpened distal tip (16) for insertion within tissue [0057], the sharpened distal tip attached to the distal end of the needle and comprising a material which will leave an artifact under magnetic resonance imaging [0062]; and a cutter (11), movable within the cutter lumen [0063]. However, Miller et al. fails to disclose the distal tip having a cavity in which the artifact creating material is disposed. Loos et al. discloses a biopsy device that is compatible for use with a magnetic resonance imaging machine comprising a needle. Loos et al. discloses the needle having a distal tip having a hollow cavity and the hollow cavity is shown to be partially filled with a material (93) that will leave an artifact under MRI (Figure 8; Col. 6, lines 25 – 33). It can be seen in the cross-section of the needle shown in Figure 8 that the material (93) is in fact located within the distal tip of the hollow needle (85). This cross-sectional figure of the needle shows that the phrase “hollow needle” (Col. 6, line 26) makes reference to the fact that there is no solid material forming the needle between the outer surface and the surface defining the interior lumen, not that there is an interior lumen for the thin rod (87) to pass through. Loos et al. discloses gadolinium to be a suitable material (Col. 6, lines 36 – 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal tip of the needle as disclosed by Miller et al. to contain a hollow cavity filled with the material which will leave an artifact as taught by Loos et al. so that the user can check whether or not the tip is located within the area of the tumor (Col. 6, lines 24 – 41).

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8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 5,534,778 to Loos et al. as applied to claim 5 above, and further in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claim 6, Miller et al. in view of Loos et al. discloses an MRI compatible device comprising a needle including a non-metallic material [0062] but does not specify the non-metallic material. Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Miller et al. in view of Loos et al. of a thermoplastic as taught by Gillies et al. or any MRI compatible material as desired.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 5,534,778 to Loos et al. as applied to claim 5 above, and further in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claim 7, Miller et al. in view of Loos et al. discloses an MRI compatible device comprising a needle including a non-metallic material [0062] but does not specify the non-metallic material. Werne discloses an MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Miller et al. in view of Loos et al.

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of a glass fiber reinforced polymer resin as taught by Werne or any MRI compatible material as desired.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claim 16, Miller et al. discloses an MRI compatible device comprising a needle including a non-metallic material [0062] but does not specify the non-metallic material. Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Miller et al. of a thermoplastic as taught by Gilles et al. or any MRI compatible material as desired.

11. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0082519 A1 to Miller et al. in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 17 and 18, Miller et al. discloses an MRI compatible device comprising a needle including a non-metallic material [0062] but does not specify the non-metallic material. Miller et al. additionally fails to disclose the artifact inducing material being selected from the group consisting of gadolinium, titanium, aluminum, copper, brass and bronze. Werne discloses an MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). Werne discloses using gadolinium to create an artifact under MRI (Col. 7, lines 24 – 40). The selection of a known material based upon its suitability for the intended use is a design

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consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to use gadolinium to induce an artifact and to form the needle as disclosed by Miller et al. of a glass fiber reinforced polymer resin as taught by Werne or any material suitable or the intended purpose.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,577,637 to Mueller, Jr. discloses a material that will leave an artifact under imaging being disposed in a cavity within the distal tip of the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

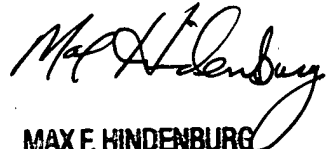
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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